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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,344	09/03/1999	YOSHIHIDE HAYASHIZAKI	024705-077	6838

7590

12/20/2002

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/20/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/254,344

Applicant(s)

HAYASHIZAKI ET AL.

Examiner

Richard G Hutson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4, 5, 11-23, 26 and 27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 11-23 is/are allowed.
- 6) ☒ Claim(s) 4, 5, 26, 27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 22.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Applicants filing of a substitute specification on May 20, 2002 is acknowledged. Applicants amendment of the specification, cancellation of claims 1, 3, 7-10, 24, 25 and 28 and the amendment of claims 4, 12, 15, 17, 19, 21, 23 and 26, Paper No. 23, 11/22/2002, is acknowledged. Claims 4, 5, 11-23, 26 and 27 are still at issue and are present for examination.

Applicants' arguments filed on 11/22/2002, Paper No. 23, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities:

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth: The following portions of the specification list sequences which appear to meet the definition for a amino acid sequence, but do not have an associated SEQ ID NO: Page 13, lines 15-18; page 35, 3 lines from bottom.

Appropriate correction is required.

Claim Objections

Claim 4 is objected to because of the following informalities: Claim 4 recites "...wild type RNA_polymerase..." and "...has been_replaced...". It is believed that this should be "...wild type RNA polymerase..." and "...has been replaced...".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4, 5, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 4, 5, 26 and 27 are directed to all possible RNA polymerases consisting of a wild type RNA polymerase wherein at least one of amino acid in a loop between helix Y and helix Z and/or an amino acid in a loop between helix Z and helix AA in the wild type RNA polymerase has been replaced with tyrosine to enhance the ability of the wild type polymerase to incorporate 3'-deoxyribonucleotides and derivatives thereof in comparison with the corresponding wild type RNA polymerase.(claim 4), wherein the replaced amino acid is phenylalanine (claim 5) or those RNA polymerase mutants

corresponding to mutations at positions 641-667 of SEQ ID NO: 2 of T7 phage (claims 26 and 27). The specification, however, only provides the representative species of mutant RNA polymerases derived from the T7, T3, SP6 and K11 phage RNA polymerases, encompassed by these claims. There is no disclosure of any particular structure to function/activity relationship, beyond the specific mutant species disclosed. The specification also fails to describe additional representative species of these mutant polymerases by any identifying structural characteristics or properties other than the activities recited in claim 4, for which no predictability of structure is apparent. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention which encompasses all wildtype polymerases from all organisms with a tyrosine substitution of an amino acid in a loop between helix Y and helix Z and/or an amino acid in a loop between helix Z and helix AA of the wildtype RNA polymerase, wherein said substitution results in an enhanced ability for incorporating 3'-deoxyribonucleotides.

It is acknowledged that a similar rejection was made in the previous office action, Paper No. 13, 12/18/2001, and traversed in applicants response, Paper No. 16, 5/20/2002. Upon further review and consideration the rejection has been reapplied to claims 4, 5, 26 and 27 as they currently exist.

Applicants traversed the previous rejection on the basis that applicants have amended the claims to more precisely define the region in which the substantive

modification has been made and thus the structural and functional characterization is contained in the claims. Applicants further argue that methods for amino acid modification or mutation and screening for such mutants is common in the art and applicants submit that they have concretely demonstrated at least 4 RNA polymerase modifications within the region in a loop between helix Y and helix Z and/or a loop between helix Z and helix AA and in amino acids 641-667. This argument is not persuasive in as much as applicants disclosure of mutants of the T7, T3, K11 and SP6 RNA polymerases, does not adequately describe similar mutations of any RNA polymerase which includes variants of all known RNA polymerases, from any organism, as well as those RNA polymerases and variants yet to be discovered. Applicants argument with respect to the structure of the region of the wildtype RNA polymerase to be mutated is not sufficient to adequately describe all of the encompassed RNA polymerase mutants and how this structure relates the overall structure of any RNA polymerase.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read "Richard Hutson", with a horizontal line extending to the right.

Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
December 18, 2002